DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2015

Viscus Biologies LLC
Ms. Elaine Duncan
Paladian Medical Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K140820
Trade/Device Name: XenoMem™ Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 24, 2015
Received: June 25, 2015

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Pending

Device Name

XenoMem(tm) Wound Matrix

Indications for Use *(Describe)*
XenoMem™ Wound Matrix is indicated for the management of wounds including:
• Partial and full-thickness wounds;
• Pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers;
• Tunnelled/undermined wounds
• Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence),
• Trauma wounds (abrasions, lacerations, second-degree burns, skin tears);
• Draining wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY TRADITIONAL 510(k)

Submitter- Manufacturer: Viscus Biologics LLC,
Peter Gingras, CEO
Viscus Biologics LLC**,** Dayton**,**
OH 45402**,** USA**.**

Tel: +1 216 658 4111

Submitted by and Contact Person

Elaine Duncan
Paladin Medical, Inc.
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Stillwater, MN 55082
715-549-6035
715-549-5380

CONTACT PERSON:	**Elaine Duncan**
DATE PREPARED:	**June 26, 2015**
TRADE NAME:	**XenoMem™ Wound Matrix**
COMMON NAME:	Topical Wound Dressing
CLASSIFICATION NAME:	Dressing, Wound, Collagen
REGULATION	Unclassified
PROCODE and CLASS	General and Plastic Surgery, KGN: Unclassified

INDICATIONS FOR USE:

XenoMem™ Wound Matrix is indicated for the management of wounds including:

- Partial and full-thickness wounds;
- Pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers;
- Tunnelled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence),
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears);
- Draining wounds.

DESCRIPTION of the DEVICE:

XenoMem™ Wound Matrix is an acellular, porcine peritoneal matrix, supplied sterile to maintain and support an environment for wound management. It consists of an extracellular tissue matrix, derived from porcine peritoneum. XenoMem™ Wound Matrix porcine peritoneal membrane provides a robust biological matrix that allows for easier handling during preparation and application of the wound dressing. The membrane has undergone a decellularisation, viral inactivation and a freeze-drying process in order to remove donor genetic material, in a non-destructive manner, so as

510(k) Summary-Continued

to maintain the structure and function of the tissue. XenoMem is sterilized via gamma irradiation and sold for prescription only.

SUBSTANTIALLY EQUIVALENT TO:

XenoMem™ Wound Matrix is substantially equivalent to Oasis® Wound Matrix, cleared with Special 510(k) K061711, which is in turn based on SS Matrix cleared via Traditional 510(k) K020732. Oasis Ultra, a line extension, is a triple layer version of Oasis Wound Matrix. Cook Biotech, Inc. manufactures these predicate devices. XenoMem™ Wound Matrix has the same indications, intended use, and the same or similar technological characteristics, principles of operation and performance properties to the Oasis-predicates. K112888 (Kensey-Nash Meso Wound Matrix) and K094061 (Kensey-Nash ECM Surgical Patch) are included as Reference Predicates because these devices are also manufactured from porcine peritoneum.

Oasis® Wound Matrix **K061711/K020732** **Cook Biotech, Inc.**	**XenoMem™ Wound Matrix** **Pending** **Viscus Biologics, LLC**
Indication: The Oasis Wound Matrix is intended for the management of wounds including: • Partial and full thickness wounds; • Pressure ulcers; • Venous ulcers • Diabetic ulcers • Chronic vascular ulcers; • Tunneled, undermined wounds; • Surgical wounds (donar sites/grafts, post Moh's surgery, post-laser surgery, podiatric, wound dehiscence); • Trauma wounds (abrasions, laceration, second-degree burns, and skin tears) • Draining wounds. The device is intended for one-time use.	Indication: XenoMem™ Wound Matrix is indicated for the management of wounds including: • Partial and full thickness wounds: • Pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers; • Tunneled/ undermined wounds • Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, laceration, second-degree burns, and skin tears) • Draining wounds.
Material and Origin Non Cross Linked Extra Cellular Matrix Porcine Small Intestinal Submucosa	Material and Origin Non Cross Linked Extra Cellular Matrix Porcine Peritoneal Membrane
Nominal Size 3 cm X 3.5 cm 3 cm X 7 cm	Nominal Size 3 cm X 3.5 cm 3 cm X 7 cm 7 X 10 cm 10 cm X 15 cm
Fenestrated	Sold non-fenestrated; Can be fenestrated for conformability; see IFU
Sterilization method ETO	Sterilization method Gamma

510(k) Summary-Continued

SUMMARY OF TESTING and RESULTS SUPPORTING SUBSTANTIAL EQUIVALENCE:

Evaluation to Demonstrate Substantial Equivalence	Conclusion
1) tensile strength (with and without fenestration),	Met requirements
2) thickness	Met requirements
3) residual DNA analysis	Met requirements
4) packaging validation and post shelf-life product performance	Met requirements
5) sterility validation to SAL 10^{-6}	Met requirements
6) biocompatibility per ISO 10993-1 & FDA guidance	Met requirements
7) residual chemical risk assessment	Risks deemed acceptable
8) viral inactivation studies.	Reduced to acceptable levels
9) differential scanning calorimetry (DSC)	Met requirements

Therefore, it is concluded that results of testing and comparative analysis have shown that any technological differences between the XenoMem™ and Oasis® wound dressing do not change the intended therapeutic use and do not introduce any new issues of safety and effectiveness.